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**3. 510(K) SUMMARY**

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- 1. Applicant/Sponsor:** Corin USA  
10500 University Center Drive  
Suite 190  
Tampa, Florida 33612  
Establishment Registration No.: 1056629
- 2. Contact Person:** Lucinda Gerber  
Regulatory Affairs Associate  
Corin USA  
813-977-4469  
[lucinda.gerber@coringroup.com](mailto:lucinda.gerber@coringroup.com)
- 3. Date:** October 13, 2011
- 4. Proprietary Name:** Unity™ Total Knee System
- 5. Common Name:** Knee Prosthesis
- 6. Classification Name:** Knee joint patella femorotibial polymer/metal/polymer semi- constrained cemented prosthesis (21CFR888.3560)
- 7. Legally Marketed Devices to which Substantial Equivalence is claimed:**
- Triathlon PS TKA System (K031729)
  - Triathlon CR TKA System (K040267)
  - Triathlon CR sz 1 Tibial Insert (K042883)
  - Triathlon PS sz 1 Tibial Insert (K050539)
  - Scorpion CR TKA System (K974556)
  - Scorpion PS TKA System (K962152)
  - Scorpion NRG System (K042343)
  - Scorpion TS (K994128)
- 8. Device Description:**
- The Corin Unity Knee System is a fixed bearing total knee replacement system that consists of a femoral component, tibial insert, tibial tray and all-polyethylene patellar component for

use in primary total knee arthroplasty. The Unity Knee System is provided in two variants, cruciate retaining (CR) and posterior stabilized (PS). The Unity CR Total Knee System is intended to accommodate the posterior cruciate ligament (PCL) if it is present. The Unity posterior stabilized variant is utilized when total knee replacement is indicated, and the posterior cruciate ligament is non-functioning or absent, resulting in joint instability. The Unity system patellar component is optional and is used in situations where replacement of the articular surface of the patella is required. The system also provides augment components including femoral wedges, tibial wedges, a short keel extension and stem extensions with offset connections.

#### **9. Intended Use / Indications:**

The Unity Total Knee System is intended for use in total knee arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged knee joint articulation where there is evidence of sufficient sound bone to seat and support the components.

General total knee arthroplasty indications include:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function
- Revision of previous unsuccessful knee replacement or other procedure, where soft tissue stability is adequate
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques
- The posterior stabilized variant is also indicated for PCL instability requiring implant bearing surface geometries with increased anterior-posterior constraint and absent or non-functioning posterior cruciate ligament

The Unity Total Knee System is indicated for cemented, single use only.

#### **10. Summary of Technologies/Substantial Equivalence:**

The Unity Total Knee System has the same intended use and indications and is manufactured from the same materials as the respective cruciate retaining and posterior stabilized predicates Triathlon (CR: K040267, K042883; PS: K031729, K050539) and Scorpio (CR: K974556; PS: K962152, K042343) Total Knee Systems. The range of sizes

K113060

available for the Unity Total Knee System falls within the range cleared for the Triathlon and Scorpio devices and the Unity Total Knee System is similar to the predicate devices in regards to design. Based on these similarities, Corin believes that the Unity Total Knee System is substantially equivalent to the predicate devices.

**11. Non-Clinical Testing:**

Non-clinical testing and analysis are provided, including bench testing for both the cruciate retaining and the posterior stabilized designs. Testing was completed in accordance with ASTM F2083 Standard Specification for Total Knee Prosthesis and included component function for femoral, tibial tray and tibial insert (fatigue, endurance and deformation, contact area and contact pressure, range of motion, constraint). Testing also included wear testing of the UHMWPE tibial insert and integrity of connecting mechanisms for static and dynamic shear tests, bending tests, mechanical stop and disassociation. The results of this testing show that the Unity Total Knee System is expected to be safe and effective for the proposed indications and is substantially equivalent to the predicate devices.

**12. Clinical Testing:**

Clinical testing was not necessary to determine substantial equivalence between the Unity Total Knee System and the predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

February 24, 2014

Corin, USA  
Ms. Lucinda Gerber, BA  
Regulatory Affairs Associate  
10500 University Center Drive, Suite 190  
Tampa, Florida 33612

Re: K113060

Trade/Device Name: Unity™ Total Knee System

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained  
cemented prosthesis

Regulatory Class: Class II

Product Code: JWH

Dated: August 28, 2012

Received: August 29, 2012

Dear Ms. Gerber:

This letter corrects our substantially equivalent letter of September 10, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Lori A. Wiggins**

for  
Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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## 2. INDICATIONS FOR USE

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510(k) Number (if known): K113060

Device Name: Unity™ Total Knee System

### Indications for Use:

The Unity Total Knee System is intended for use in total knee arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged knee joint articulation where there is evidence of sufficient sound bone to seat and support the components.

General total knee arthroplasty indications include:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
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The Unity Total Knee System is indicated for cemented, single use only.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Elizabeth L. Frank -S**

Division of Orthopedic Devices

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